REMARKS/ARGUMENTS

The action by the Examiner of this application, together with the cited references, have been given careful consideration. Following such consideration, claims 17, 20-22, 25, 27 and 28 have been amended. Claims 23, 24 and 26 are unchanged by the present amendment and claims 18 and 19 are cancelled. Claims 1-16 were previously cancelled. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application. A *Request for Continued Examination* (RCE) accompanies this Response.

The present invention provides a method by which vaporized hydrogen peroxide and ozone are supplied to a region to effect inactivation of biocontamination therein. The method of the claimed invention ***simultaneously*** introduces both vaporized hydrogen peroxide and ozone gas to the region using a closed loop system. It should be appreciated that the *simultaneous* introduction of both vaporized hydrogen peroxide and ozone gas into a region provides synergistic effects that are not present when vaporized hydrogen peroxide and ozone gas are used individually to effect inactivation of biocontamination within a region. In this respect, it is believed that when vaporized hydrogen peroxide and ozone react with each other a hydroxyl radical ($2OH^*$) is formed that acts as an efficient sterilant. This reaction occurs as follows:

$$H_2O_2 + O_3 \rightarrow 2OH^* + (3/2)O_2 \rightarrow H_2O + 2O_2$$

Moreover, the ozone gas generated in accordance with the present invention is produced under dry conditions that promote the production of ozone. The ozone generated under dry conditions is then subsequently used in humid conditions that promote the bleaching qualities of the ozone. Since vaporized hydrogen peroxide is formed from an aqueous solution of hydrogen peroxide, the humid conditions are produced as part of the vaporization process.

Rejection Under 35 U.S.C. 112, First Paragraph

The Examiner has rejected claims 18 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner indicates that the disclosure does not teach that the steps of generating ozone gas and introducing vaporized hydrogen peroxide are applied in alternating and contemporaneous manners. Claims

18 and 19 have now been cancelled. However, claim 17 has been amended to require the step of "simultaneously introducing said vaporized hydrogen peroxide and said ozone gas into the region." The Examiner's attention is drawn to paragraph [0001] of the specification that recites the "simultaneous application of ozone and vaporized hydrogen peroxide." Paragraph [0019] of the specification refers to a system operable to decontaminate with "a combination of vaporized hydrogen peroxide and ozone." The Examiner's attention is also drawn to paragraphs [0039]-[0047] of the specification that describe in detail the applicant's method for biocontamination inactivation wherein both vaporized hydrogen peroxide and ozone are introduced into a region defined by an isolator or room 22. It is respectfully submitted that the foregoing disclosure complies with the requirements of 35 U.S.C. 112, first paragraph. Therefore, the Examiner is requested to now withdraw the rejection.

Rejection Under 35 U.S.C. 103

The Examiner has rejected claims 17-20, 22-23 and 25-28 as being obvious in view of the combined teachings of Pai et al. (US 6,156,267), Childers (WO97/47331) and Kazi et al. (US 5,578,280). Claim 21 has been rejected as being obvious in view of the combined teachings of Pai et al., Childers, Kazi et al. and Bell et al. (US 5,516,493). Furthermore, claim 24 has been rejected as being obvious in view of the combined teachings of Pai et al, Childers, Kazi et al., and Karlson (US 5,069,880).

With respect to claim 17, it is respectfully submitted that none of the cited references, taken individually or in combination, anticipates or renders obvious the claimed method, wherein both vaporized hydrogen peroxide and ozone gas are introduced into a carrier gas of a closed loop system, and *simultaneously* introduced into a region.

In the present invention, moisture is first removed from a carrier using a drying means located upstream of an ozone generator. The ozone generator uses oxygen molecules in the dried carrier gas to generate ozone gas, thereby introducing ozone into the carrier gas. A vaporizer located downstream of the ozone generator then introduces vaporized hydrogen peroxide into the carrier gas having ozone gas produced by the ozone generator. The vaporized hydrogen peroxide and ozone gas are *simultaneously* introduced into a region wherein biocontamination inactivation is effected.

Pai et al. disclose a system and method for real-time monitoring and control of anti-microbial cycle parameters within a load-simulation device 6. The system and method simulate the same conditions as those within an acceptable standard challenge load to be sterilized. Pai et al. provide no teaching with respect to introducing both ozone gas and vaporized hydrogen peroxide into a carrier gas circulating through ***closed loop system*** and ***simultaneously introducing*** the vaporized hydrogen peroxide and ozone gas into a region wherein biocontamination inactivation is effected. Furthermore, Pai et al. provide no teaching with respect to ***removing moisture*** from a carrier gas circulating in a conduit of a closed loop system, in advance of generating ozone gas using oxygen molecules in the carrier gas.

The Examiner relies upon Childers for teaching recirculation of vaporized hydrogen peroxide in combination with a carrier gas through a closed loop conduit. The Examiner also relies upon Childers for disclosing "partially and selectively drying" of the carrier gas in response to sterilization parameters.

A close examination of Childers reveals that Childers' system and method "only partially and selectively" dries the carrier gas in response to system parameters (i.e., chamber temperature, relative humidity, and vapor concentration) in order to maintain a predetermined percent of sterilant vapor saturation in the sterilization chamber. In Childers' method, "the water vapor concentration of the carrier gas entering the chamber may be higher than was previously obtained or desired." Referring to page 9, lines 17 *et seq.* of Childers, the following is disclosed (emphasis added):

> The adjustable drying unit 24 **serves selectively to remove moisture from the carrier gas flow** entering the chamber. The drying unit preferably comprises a variable valve 26 having a first flow path A-B and a second flow path B-C, and a regenerative air dryer 28 having an inlet port 30 and an outlet port 32. The air dryer 28 is positioned downstream of the variable valve 26. A first fluid flow line 34 connects the first flow path to the dryer inlet port 30, while **a second fluid flow line 36 bypasses the dryer 28** and connects to the conduit circuit downstream of the drying unit. By varying the amount of flow through the first and second valve flow paths, a **selected portion of the carrier gas flow can be routed to bypass the dryer 28**. Alternately, a rate of drying, e.g., condensing of water vapor, by the dryer 28 can be adjusted directly. In this

> way, the humidity of the carrier gas can be regulated or adjusted (i.e., the carrier gas can be selectively dried) to **maintain a predetermined percent saturation of sterilant vapor in the chamber** as the sterilization cycle proceeds.

Childers provides a bypass line 36 to allow a portion of the carrier gas to bypass dryer 28, thereby maintaining the moisture in the bypassed carrier gas. In contrast to Childers' system, the applicant's invention as now defined by claim 17 requires the drying means to remove moisture from **"all of the carrier gas"** received by the ozone generator. Thus, Childers teaches away from the claimed invention by providing means (i.e., bypass line 36) to maintain a level of moisture within the carrier gas, rather than to subject all of the carrier gas to moisture removal.

Moreover, Childers does not provide any teaching to remove moisture prior to an ozone generating process. As indicated above, the present invention removes moisture from the carrier gas before ozone generation in order to promote the production of ozone by the ozone generator.

In the claimed invention vaporized hydrogen peroxide and ozone gas are *simultaneously introduced* into a region. Humid conditions in the region advantageously promote the bleaching qualities of the ozone. As indicated above, the humid conditions are created upon the vaporization of the aqueous mixture of hydrogen peroxide. Thus, the combination of vaporized hydrogen peroxide and ozone within the region provides synergistic effects. As discussed above, it is also believed that vaporized hydrogen peroxide and ozone will react with each other to produce a hydroxyl radical ($2OH^*$) that acts as an efficient sterilant. Furthermore, drying the carrier gas prior to producing ozone enhances the production of the ozone by the ozone generator.

Therefore, it is respectfully submitted that the present invention as defined by claim 17 provides unexpected and superior results as compared to existing systems.

The Examiner has noted in the *Response to Arguments* that the "instant claims do not require that all the circulating gas to pass through the dryer as applicant argues." As discussed above, independent claim 17 has now been amended to clarify that the drying means "removes moisture from all of the carrier gas to be received by the ozone generator."

It is respectfully submitted that none of the other cited references provide for the deficiencies discussed above.

In view of the foregoing comments, it is respectfully submitted that the cited references, taken individually or in combination, fail to anticipate or render obvious the applicant's invention as set forth in amended claim 17.

Claims 18-28 depend from claim 17. Thus, it is respectfully submitted that these claims are likewise patentable over the cited references for at least the reasons discussed above in connection with claim 17.

Conclusion

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8613US.

Respectfully submitted,

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Michael A. Jaffe
Registration No. 36,326

Kusner & Jaffe
Highland Place – Suite 310
6151 Wilson Mills Road
Highland Heights, Ohio 44143
(440) 684-1090 (phone)
(440) 684-1095 (fax)

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